



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,234	01/11/2002	Paola Elisabettni	DI-5782	8974

29200 7590 05/18/2004

BAXTER HEALTHCARE CORPORATION  
RENAL DIVISION  
1 BAXTER PARKWAY  
DF3-3E  
DEERFIELD, IL 60015

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/044,234

Applicant(s)

ELISABETTINI ET AL.

Examiner

Frank I Choi

Art Unit

1616

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.


Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s).

10. ☐ Other: \_\_\_\_\_



**S. MARK CLARDY**  
**PATENT EXAMINER**  
**GROUP 1200**  
1616

Continuation of 3. Applicant's reply has overcome the following rejection(s): 102/103 inherency rejection of Claims 2,3,17-19, 24,28,29,45-47,55-57 over Watanabe et al..

Continuation of 5. does NOT place the application in condition for allowance because: Examiner has duly considered Applicant's argument's but deem them unpersuasive. With respect the rejection of claims 1-72 under 35 USC 112, second paragraph, the issue is not whether one of ordinary skill in the art would consider the claims as directed to be indefinite. The issue is that Applicant in its arguments has argued that the claims are not rejectable because of claim limitations which are not set forth in all of the claims, i.e. because that some of the claims recite that solution includes potassium in each component and equimolar amounts of sodium that all of the claims are not rejectable (See Remarks, Paper No. 10/20/2003, pgs. 4, 5). Applicant's response does not address this issue. With respect to the 102 rejection, there is nothing that bars one from using the same reference in both a 102/103 inherency rejection and a 103 rejection. The fact that the rejected claims are also obvious does not take away from the fact that they are anticipated over Watanabe et al.. As such, Applicant's argument is without merit. Applicant argues that the claimed invention relates to bicarbonate solutions that include at least two separate solution components, such as a bicarbonate concentrate and an electrolyte concentrate as required by independent claims 1,17,44,55. Watanabe also expressly discloses separate solutions of bicarbonate and electrolyte which are mixed together (Watanabe et al. Column 6, lines 13-68, Column 7-10). Further, Watanabe expressly discloses embodiments in which potassium is included. Claim 16 is a composition claim, as such, the intended use does not patentably distinguish over the prior art. With respect to claims 44 and 55, Applicant is reminded that claims limitations are interpreted broadly for purposes of prosecution. The limitation hemofiltration, i.e. blood filtration, clearly includes dialysis and is not limited to CRRT. With respect to Applicant's obviousness arguments relative to the 102/103 inherency rejection, Applicant is reminded that the Graham v. John Deere factors are not applicable in an inherency rejection, as such, Applicant's arguments do not overcome said rejection. As such, the 102/103 rejection of claims 1,11,15,16, 44, 52 is maintained. With respect to the 103 rejection, the motivation to modify the art does not have to be the same as that which motivated Applicant. Further, as indicated in the prior Office Action, it is improper to argue the Watanabe et al. reference in isolation to the other references. The mere fact that Watanabe et al. may or may not be deficient in one or more aspects of the claimed invention does not overcome the rejection as the rejection is based on the combined teachings of the prior references. The prior art teaches that potassium can be either component or both, as such, one of ordinary skill in the art would have been motivated to place potassium as desired with the expectation of formulating a suitable dialysis or hemofiltration solution. The prior art also teaches use of sodium in the bicarbonate component and in electrolyte component. There is nothing in Feriani in view of the other prior art which precludes sodium from being in both components, as such, one of ordinary skill in the art would have been motivated to add sodium to one or both of the components as desired including equimolar amounts with the expectation of formulating a suitable dialysis or hemofiltration solution. Applicant has not shown any new or unexpected results of having potassium in either one or both of the components or equimolar amounts of sodium. Feriani discloses physically arranging the two solutions so that both must be mixed prior to use. As such, the 103 rejection of claims 1-72 is maintained.